

**INFORMATION DISCLOSURE STATEMENT**

Applicant : Thomas F. Fangrow, et al.
App. No. : 09/879,364
Filed : June 12, 2001
For : MEDICAL VALVE WITH POSITIVE
FLOW CHARACTERISTICS
Examiner : Kevin C. Sirmons
Group Art Unit : 3763

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Enclosed is form PTO-1449 listing forty (40) references that are also enclosed. As provided by 37 C.F.R. § 1.97(h), the filing of this Information Disclosure Statement shall not be construed as an admission that the cited references are material to patentability.

A patent related to the present application has been involved in litigation between the assignee, ICU Medical, Inc., and an accused infringer of the patent, B. Braun Medical, Inc. Four of the enclosed documents relate to certain invalidity allegations raised by Braun during the litigation regarding a version of Braun's Ultrasite® product. The U.S. District Court for the Northern District of California has entered a Protective Order which prohibits disclosure of certain confidential information from the lawsuit. Under the terms of the protective order, such confidential information is available to litigation counsel, but not to the inventors of this application or to ICU Medical, Inc. Accordingly, Applicants have submitted herewith non-confidential excerpts relating to the foregoing invalidity allegations by Braun.

Braun contends that a version of the Ultrasite® product was launched in October 1996 and is prior art under either 35 U.S.C. § 102(a) or (b), and that "earlier Ultrasite® activities" in 1993 separately qualify as prior art under 35 U.S.C. § 102(g). See Footnote 3 of Braun's Memorandum of Points and Authorities in support of its Motion for Summary Adjudication on the Priority Date of the '048 Patent and Defendant's Patent L.R. 3-3 Preliminary Invalidity Contentions. Based upon the dates alleged by Braun, the enclosed document entitled

Appl. No. :
Filed :

Docket No.
Customer No. 20,995

"Ultrasite™ System" is believed to illustrate the device relating to Braun's invalidity allegations under 35 U.S.C. §§ 102(a) and 102(b). The enclosed document entitled "Capless Backcheck Valve" is believed to illustrate the Ultrasite design relating to Braun's invalidity allegations under 35 U.S.C. § 102(g).

Braun has also alleged that ICU Medical committed inequitable conduct by not disclosing to the U.S. Patent and Trademark Office information regarding a particular version of the Ultrasite® device. Braun alleges that ICU's knowledge of the alleged materiality of that version of the Ultrasite® device is demonstrated by a form submitted by ICU to the U.S. Food and Drug Administration after the earliest priority date of the present application. The enclosed F.D.A. 510(k) form indicated that the B. Braun V2 Ultrasite Injection Site (K955585) was an "Equivalent Device" to ICU Medical's CLC 2000, for purposes of F.D.A. regulations.

This Information Disclosure Statement is being filed with an RCE or within three months of the filing date of this application and no fee is required in accordance with 37 C.F.R. § 1.97(b)(1), (b)(2), or (b)(4).

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 10/9/03

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FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.
ICUMM.78CP1CAPPLICATION NO.
09/879,364INFORMATION DISCLOSURE STATEMENT
BY APPLICANTAPPLICANT
Thomas F. Fangrow et al.FILING DATE
June 12, 2001GROUP
3763

(USE SEVERAL SHEETS IF NECESSARY)

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (IF APPROPRIATE)
	1	2,847,995	08/58	Adams			
	2	2,999,499	09/61	Willet			
	3	3,193,154	07/65	Bross			
	4	3,788,519	01/74	Mengel			
	5	3,831,629	08/74	Mackal et al.			
	6	3,986,508	10/76	Barrington			
	7	4,306,705	12/81	Svensson			
	8	4,334,551	06/82	Ofuster			
	9	4,512,766	04/85	Vilancourt			
	10	4,610,469	09/86	Wolff-Mooji			
	11	4,666,429	05/87	Stone			
	12	4,874,377	10/89	Newgard			
	13	4,915,687	04/90	Sivert			
	14	4,917,668	04/90	Haindl			
	15	5,006,114	04/09/91	Rogers et al.			
	16	5,065,783	11/91	Ogle, II			
	17	5,154,703	10/92	Bonaldo			
	18	5,163,922	11/92	McElveen			
	19	5,242,432	09/93	DeFrank			
	20	5,401,245	03/95	Haining			
	21	5,470,319	11/95	Mayer			
	22	5,509,433	04/23/96	Paradis			
	23	5,549,566	08/96	Lynn			
	24	5,569,235	10/29/96	Ross et al.			
	25	6,036,171	03/00	Weinheimer			
	26	6,050,978	04/00	Orr et al.			
	27	6,079,432	06/00	Paradis			

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EXAMINER

DATE CONSIDERED

*EXAMINER: INITIAL IF CITATION CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP 609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

FORM PTO-1449

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U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (IF APPROPRIATE)
	28	6,089,541	07/00	Weinheimer			
	29	6,113,068	09/00	Ryan			
	30	6,117,114	09/00	Paradis			
	31	6,245,048	06/01	Fangrow			

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	32	HU P9 902 203	10/99	Hungary				
	33	HU P9 902 031	10/99	Hungary				
	34	WO 97/21463	06/97	PCT				
	35	WO 97/21464	06/97	PCT				
	36	WO 99/58186	11/99	PCT				

EXAMINER INITIAL	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)	
	37	Excerpt from Braun's Memorandum of Points and Authorities in Support of its Motion for Summary Adjudication on the Priority Date of the '048 Patent
	38	Ultrasite™ Systems "How It Works"
	39	Capless Backcheck Valve
	40	F.D.A. 510(k) Summary of Safety and Effectiveness

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FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. ICUMM.078CP1RI	APPLICATION NO. 10/217,213
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (USE SEVERAL SHEETS IF NECESSARY)		APPLICANT Thomas F. Fangrow et al.	
		FILING DATE August 9, 2002	GROUP 3763

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (IF APPROPRIATE)
	28	6,089,541	07/00	Weinheimer			
	29	6,113,068	09/00	Ryan			
	30	6,117,114	09/00	Paradis			
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	34	WO 97/21463	06/97	PCT				
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	37	Excerpt from Braun's Memorandum of Points and Authorities in Support of its Motion for Summary Adjudication on the Priority Date of the '048 Patent
	38	Ultrasite™ Systems "How It Works"
	39	Capless Backcheck Valve
	40	F.D.A. 510(k) Summary of Safety and Effectiveness

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